

REMARKS

Claims 29-34 are currently pending in the application. Claims 30, 31, 32 and 34 have been cancelled. Claim 29 has been amended to more particularly point out and distinctly and clearly claim the invention. The amendments are made without prejudice, do not present any new matter, and are not made to overcome any prior art rejection.

Claims 29-34 are rejected under 35 USC §112. The Office Action alleges that in claim 29, it is unclear (from the specification) as to the cutoff of 9 for the optical density (OD) as measured by IHC. In response thereto, Applicants have amended the claim to more clearly recite an optical density of 10 as the cut-off. Support for this amendment can be found on page 15, lines 6-13 of the specification. The Office Action further requests additional specificity with respect to the type of IHC techniques performed to obtain the optical density amounts. Applicants have amended the claims accordingly. Support for this amendment can be found on page 12, lines 2-18. The amendments are made without prejudice, do not present any new matter, and are not made to overcome any prior art rejection.

Claim 29 is further rejected as allegedly lacking a treatment step. On the contrary, claim 29 specifically recites:

“...and *treating the subject with anti-EGFR antibody ABX-0303* when the detected HER3 expression level has an optical density less than 10 when the assay is quantitative immunohistochemistry as measured using the VMSI “I-View” detection kit and the TUNELTM assay...”

Withdrawal of this rejection is respectfully requested.

Claims 29 and 33 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Hudziak in view of Esteva, Pinkas-Kramarski, in view of Hoffmann. Applicants have amended claim 29 to specifically recite antibody ABX-303.

None of the cited references, either alone or in combination, teach or suggest the instantly claimed methods in view of the above. Hudziak does not disclose the existence of HER3, much less its use as a biomarker. Esteva does not disclose (or even suggest) that any of the biomarker patterns of expression could be used to select a subject for treatment with a molecule targeting EGFR. Pinkas-Kramarski does not even teach or suggest a treatment therapy, much less a therapy based on anti-EGFR antibody as required by the present claims. Hoffman relates to expression of receptors (such as ErbB-2 and ErbB-3) and how they are associated with TNF- α insensitivity. Thus, none of Hudziak, Esteva, Pinkas-Kramarski, or Hoffman render claim 29, as now amended, obvious. Withdrawal of this rejection is respectfully requested.

Claims 29, 30, 33, and 34 are also rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Hudziak in view of Esteva, Pinkas-Kramarski, Hoffmann, and further in view of Yang. Claims 30 and 34 have been cancelled, and the rejection will be addressed with respect to claims 29 and 33.

While Yang does admittedly recite the ABX-303 antibody, Yang's combination with Hudziak, Esteva, Pinkas-Kramarski and Hoffmann (as discussed above) simply does not suggest let alone render the currently-amended claims obvious.

Applicants therefore respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Based on the above, Applicants believe the claims are now allowable. If there are any questions or comments regarding this response, the please contact the undersigned attorney at 805-447-4128.

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